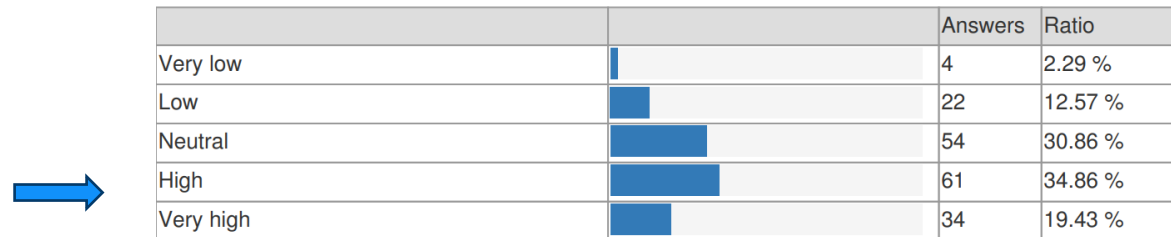


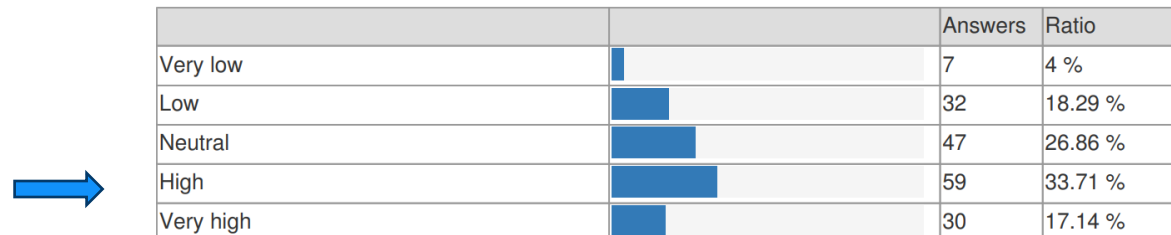
Barriers in clinical research in EU: (rare disease) investigator perspective

Results of ERICA (*European Rare Disease Research Coordination and Support Joint Action*)
WP4 Survey 2023:

- Challenges in building relationships with regulatory agencies/authorities



- Challenges in conducting clinical research that complies with regulatory requirements



Opportunities for clinical trialing in EU: investigator perspective

- Consolidation of EU pharmaceutical markets (re-imburement/tenders)
- Harmonization of MS interpretation of GDPR and successive legislation
- Harmonization and standardization of part II CTIS (i.e. ICFs should be identical)
 - PIF EU standard/ reference texts (patient rights) not needed to be incorporated/simplified
- Harmonization of CTA contracts and regulations
 - IE non-EU governing law forbidden
 - Penalties forbidden
 - Liability cap
 - Benchmark for Medical personnel (ie French CTA, Dutch CGR)